UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

KENNETH McGUIRE, et al., Plaintiffs, v. DENDREON CORPORATION, et al., Defendants.	Case No. C07-800MJP Class Action ORDER GRANTING DEFENDANTS' MOTION TO DISMISS THE CLASS ACTION COMPLAINT

This matter comes before the Court pursuant to Defendants' Motion to Dismiss the Class Action Complaint. (Dkt. No. 55.) After reviewing the moving documents, Plaintiffs' Opposition (Dkt. No. 61), Defendants' Reply (Dkt. No. 67), and all papers submitted in support thereof, and after having heard oral argument on the issues, the Court GRANTS Defendants' motion.

Background

Defendant Dendreon Corporation is a biotechnology company that develops and manufactures treatments for cancer. (Compl. ¶ 35.) The other defendants in this action are Dendreon officers and directors. Dendreon's most advanced product is Provenge, an active cellular immunotherapy for advanced prostate cancer. (Compl. ¶¶ 35-36.) Plaintiff Kenneth McGuire is the lead plaintiff in a putative class action against Defendants, representing "persons and entities who purchased the common stock of Dendreon between March 1, 2007 and May 8, 2007." (Compl. ¶¶ 10, 27.)

In November 2006, Dendreon submitted a Biologics License Application ("BLA") to the Food and Drug Administration ("FDA"). The BLA was accepted and granted priority review, with the anticipated date for completed review set on May 15, 2007 ("Complete Response

Date"). (Compl. ¶ 37.)

Part of the review process is a "Chemistry, Manufacturing, and Controls" ("CMC") inspection of an applicant's manufacturing facility, including the applicant's "manufacturing, training, product testing, support systems, and record-keeping methods." (Compl. ¶ 38.) If the FDA identifies any potential violation, it is recorded on an onsite inspection report, given to the applicant. (Compl. ¶ 39.) This report, "Form 483," notifies top management of "significant objectionable conditions." (Greene Decl., Ex. I-5, FDA Investigations Operations Manual.) The determination of whether any condition is "violative" is made not by the FDA inspector, but by the agency after considering "all circumstances, facts and evidence." (Id. at I-8.) Plaintiffs allege that "[i]n virtually every case, the issuance of a Form 483 will push back the [Complete Response Date]." (Compl. ¶ 39.)

During the week of February 12, 2007, the FDA inspected Dendreon's plant, found "various CMC violations," and issued a Form 483 to Dendreon. (Compl. ¶ 45.)

On March 1, 2007, Dendreon issued a press release stating that the FDA "will review the Biologics License Application for Provenge.... Based on the FDA's designation of Priority Review for Provenge, the Company anticipates action by the FDA approximately six months from the submission date, or by May 15, 2007." (Compl. ¶ 48; Greene Decl., Ex. A-1.) The press release did not mention the issuance of the Form 483. (See Greene Decl., Ex. A-1.)

On March 14, 2007, Dendreon filed its 2006 Form 10-K with the SEC. (Compl. ¶ 49; Greene Decl., Ex. L.) The 2006 Form 10-K listed "every... fact relevant to the BLA," including the date of application and the anticipated Complete Response Date. (Compl. ¶ 49.) Dendreon also stated in the 2006 Form 10-K that "[b]efore approving a biologics license application, the FDA will inspect the facilities... and will not approve the product unless the manufacturing facilities are in compliance." (Compl. ¶ 50; Greene Decl., Ex. L-5.) Under "Risk Factors" in the 2006 Form 10-K, Dendreon also stated that "the FDA may determine that our manufacturing staff, methods, facilities or raw materials are insufficient to warrant licensure." (Compl. ¶ 51;

Greene Decl., Ex. L-6.) The 2006 Form 10-K did not mention the issuance of the Form 483. (See Greene Decl., Ex. L.)

Also on March 14, 2007, Dendreon filed a Form 8-K with the SEC and issued a press release announcing its financial information for 2006. (Compl. ¶ 56; Greene Decl., Ex. K-5.) The press release included a section titled "Recent Highlights," and included a list of several key events, such as the submission of the Biologics License Application, the Complete Response Date, and the anticipated March 29, 2007 review of Provenge by the FDA's Cellular, Tissue and Gene Therapies Advisory Committee ("Advisory Committee"). (Compl. ¶ 56; see Greene Decl. K-5.) The press release did not include a disclosure about the Form 483. (See Greene Decl., Ex. K-5.)

On March 28, 2007, Dendreon's stock closed at $5.22 per share. (Compl. ¶ 57; Greene Decl., Ex. G-2.) On March 29, 2007, Dendreon issued a press release announcing that the Advisory Committee concluded that Provenge was both reasonably safe and effective. (Compl. ¶¶ 58-59; Greene Decl., Ex. J-6.) On March 30, 2007, Dendreon's stock price closed at $12.93 a share. (Compl. ¶ 60; Greene Decl., Ex. G-2.) Dendreon filed a Form 8-K with the SEC, which incorporated the March 29, 2007 press release. (Compl. ¶ 61; Greene Decl., Ex. J-3.)

Between April 2 and April 10, 2007, some of the Dendreon directors sold shares of their Dendreon stock. On April 2, 2007, Defendant Gold exercised options for Dendreon shares of common stock, and sold 202,000 shares. (Compl. ¶ 62.) On April 3, 2007, Defendant Bogdan Dziurzynski, a Dendreon director and Consultant for Regulatory Affairs, (Compl. ¶ 21), sold 25,000 shares of Dendreon stock at $15.32 per share. (Compl. ¶ 63.) On April 4, 2007, Defendant Ruth B. Kunath, a Dendreon director, (Compl. ¶ 22), exercised her options and sold 54,250 shares at approximately $15.00 a share. (Compl. ¶ 63.) Between April 5 and April 10, Kunath exercised additional options and sold 23,100 more shares of Dendreon stock. (Compl. ¶ 65.) On May 8, 2007, the FDA issued a Complete Response Letter to the Provenge BLA. (Compl. ¶ 67.) Dendreon's stock price closed that day at $17.74. (Compl. ¶ 68; Greene Decl.,

Ex. G-1.)

On May 9, 2007, Dendreon issued a press release announcing that the FDA had requested additional efficacy and CMC information regarding Provenge: "[t]he FDA has requested additional clinical data in support of the efficacy claim contained in the [Biologics License Application].... The FDA has also requested additional information with respect to the chemistry, manufacturing and controls section of the [Application], which the Company believes it can supply to the FDA in a timely manner." (Compl. ¶ 67; Greene Decl., Ex. E-7.) After the press release was issued, Dendreon's stock price dropped to $6.33 per share. (Compl. ¶ 68; Greene Decl., Ex. G-1.)

On May 10, 2007, several Dendreon officers participated in a conference call with investors. (Compl. ¶ 69; Greene Decl., Ex. C.) Defendant David R. Urdal, Dendreon's Senior Vice President and Chief Science Officer, (Compl. ¶ 18), stated that Dendreon had been issued the Form 483; Urdal also stated that "one of the items mentioned in the letter... was just a reminder that we needed to complete our response to all the [Form 483] items that came in the inspection" and that he believed "none of the issues are ones that will delay the approval process from a manufacturing point of view." (Compl. ¶ 69; Greene Decl., Ex. C-6.) On May 11, the stock closed at $6.11 per share. (Greene Decl., Ex. G-1.)

Plaintiffs' Complaint states two causes of action against Defendants: 1) violation of § 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5; and 2) violation of § 20(a) of the Securities Exchange Act. (Compl. ¶¶ 80-89.)

Defendants move pursuant to Fed. R. Civ. P. 12(b)(6) to dismiss Plaintiffs' claims. (Dkt. No. 55.) Defendants argue that (1) Plaintiffs have not met their pleading burden under the Private Securities Litigation Reform Act to show that Defendants made misleading statements with the requisite fraudulent scienter; (2) the alleged misrepresentations did not cause Plaintiffs' economic loss; and (3) Plaintiffs' § 20(a) claim fails as a matter of law.

Discussion

I. Threshold Issues

A. Section 10(b) Standard

When faced with a motion to dismiss an action brought under § 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), a court accepts all facts in the complaint as true. Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S.Ct. 2499, 2509 (2007). A complaint should not be dismissed if the plaintiffs can prove any set of facts to support a claim that would merit relief. Bell Atl. Corp. v. Twombly, 127 S.Ct. 1955, 1965-69 (2007).

Section 10(b) of the Exchange Act states that it is unlawful for any person to "use or employ, in connection with the purchase or sale of any security... any manipulative or deceptive device or contrivance[.]" 15 U.S.C. § 78(j)(b). Securities and Exchange Commission ("SEC") Rule 10b-5 imposes liability on any person who "make[s] any untrue statement of a material fact" or "omit[s] to state a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). A claim under Rule 10b-5 must show: (1) a material misrepresentation or omission; (2) made with a wrongful state of mind ("scienter"); (3) in connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation, i.e., a causal connection between the material misrepresentation and the loss. Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341-42 (2005).

The Private Securities Litigation Reform Act of 1995 ("PSLRA") imposes heightened pleading requirements on private actions brought under the Exchange Act. Tellabs, 127 S.Ct. at 2508. If a plaintiff alleges that the defendant made a false or misleading statement, his complaint must "(1) specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading;" and (2) "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(1)-(2). A plaintiff who argues that a statement is false or misleading because of an omission must "state with particularity all facts on which [his] belief is based." In re Silicon Graphics, Inc., 183 F.3d

970, 983 (9th Cir. 1999) (citation omitted). If the allegations in a complaint are "not sufficiently particularized or where, taken as a whole, [do] not raise a 'strong inference' that misleading statements were knowingly or [with] deliberate recklessness made to investors," the court must grant dismissal. Ronconi v. Larkin, 253 F.3d 423, 429 (9th Cir. 2001); see also 15 U.S.C. § 78u-4(b)(3)(A). Plaintiffs argue that the statements in Defendants' press releases and SEC filings were misleading because they failed to mention the issuance of the Form 483. Specifically, Plaintiffs claim that because the issuance of the Form 483 "virtually guaranteed" that Provenge would not be approved by the Complete Response Date, (Compl. ¶ 4), the statements regarding the progress of the Biologics License Application were misleading "and caused the price of Dendreon's stock during the Class Period to be artificially inflated." (Compl. ¶ 4.)

B. Judicial Notice

Defendants request that the Court take judicial notice of various documents attached to the Greene Declaration. (Dkt. No. 69; see Greene Decl., Exs. A-U.) The Court takes judicial notice of the requested documents, including the above listed press releases, filings with the SEC, conference call transcripts, stock status reports, and FDA regulatory protocols. A court may take judicial notice of documents that are referenced by the plaintiff in the complaint and whose authenticity are not in dispute, such as SEC filings, press releases, analyst reports, and conference call transcripts. See In re Wetseal, Inc., 518 F. Supp. 2d 1148, 1157 (C.D. Cal. 2007). However, the Court will not draw inferences in favor of Defendants from the judicially-noticeable facts. See Darensburg v. Metro. Transp. Com'n, 2006 WL 167657 *2 (N.D. Cal. 2006) (declining "Defendant's invitation to take judicial notice of the complex inferences that Defendant would have [the court] draw from the facts contained in those documents"). When factual findings are in dispute, "those matters of dispute are not appropriate for judicial notice." Id. (citation omitted). In this case, the Court takes judicial notice of the documents attached to the Greene Declaration, but draws no inferences in Defendants' favor from those documents.

C. Materiality of the Form 483

The parties dispute the materiality of the issuance of the Form 483. Rule 10b-5 requires that an omission or false statement be related to a "material" fact. See 17 C.F.R. § 240.10b-5. An omitted fact is related to a material fact if there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic v. Levinson, 485 U.S. 224, 231-32 (1988) (citation omitted). Defendants argue that Plaintiffs' claims are based on the false assumption that receipt of the Form 483 made the delay of FDA approval of Provenge "virtually certain." Plaintiffs argue that the issues identified in the Form 483 created a material risk that Provenge's approval would be delayed, and that even if the Form 483 did not virtually guarantee the delay, "any risk of any potential delay is material[.]" (Plfs.' Opp'n at 9.) Dendreon has not made public the issues identified in the Form 483 and neither Plaintiffs nor the Court know its contents.

The Court concludes that Dendreon's receipt of the Form 483 is material because it is a fact that "[bears] on possible delays in FDA approval." See Yanek v. Staar Surgical, Co., 388 F. Supp. 2d 1110, 1129 (C.D. Cal 2005) (holding that "[t]he facts related to the issuance of the Form 483 and the problems described therein" were material). This case is not like Anderson v. Abbott Labs., in which the Northern District of Illinois concluded that the history of company non-compliance with the FDA and the relative unimportance of the at-issue product made the issuance of a Warning Letter (a post-Form 483 notice) immaterial. 140 F. Supp. 2d 894, 902 (N.D. Ill. 2001). The FDA inspector issues a Form 483 when he observes "significant objectionable conditions." (Greene Decl., Ex. I-5.) Although the observations in the Form 483 are not final agency determinations and although Plaintiffs have failed to plead how serious the observations were, the disclosure of "significant objectionable conditions" would significantly alter the total mix of information available to the reasonable investor because it bears on potential delays in the approval of Dendreon's only near-commercial status product.

II. False or Misleading Statements

A false statement is "any untrue statement of material fact." In re Immune Response Sec. Litig., 375 F. Supp. 2d 983, 1016 (S.D. Cal. 2005) (citations and internal quotation marks omitted). A false statement also includes "when a defendant omitted to state a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading." Id. at 1016-17 (citations and internal quotation marks omitted). A statement is misleading if it "affirmatively create[s] an impression of a state of affairs that differs in a material way from the one that actually exists." Brody v. Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002). Statements that are literally true can be misleading. See id. The burden is on Plaintiffs to plead specific reasons why the statements from Defendants "were misleading or untrue, not simply why the statements were incomplete." Lipton v. Pathogenesis Corp., 284 F.3d 1027, 1035 n.14 (9th Cir. 2002) (citations and internal quotation marks omitted). Plaintiffs argue that Defendants' statements were misleading because they failed to disclose the issuance of the Form 483 and the corollary risk that Provenge would not be approved by the Complete Response Date. (Compl. ¶ 4.)

A. Group Pleading

As a threshold matter, the parties dispute the extent to which the allegedly misleading statements can be attributed to Defendants Dziurzynski and Kunath.[1] Under the group pleading doctrine, there is a presumption that the allegedly false and misleading "group-published information" is the "collective action of officers and directors." In re GlenFed, Inc. Sec. Litig., 60 F.3d 591, 593 (9th Cir. 1995). Group published information is "information contained in documents such as annual reports and press releases." In re BP Prudhoe Bay Royalty Trust Sec. Litig, 2007 WL 3171435 *7 (W.D. Wash 2007) (citations omitted). If a plaintiff successfully pleads facts allowing for the presumption, he "can attribute statements to individual defendants based on their positions, rather than pleading facts that show that a defendant actually made,

[1] Defendants do not challenge application of the doctrine to any of the other individually-named Defendants.

authored, or communicated a statement." Id. In order to invoke this presumption for outside directors (i.e., non-officer directors), a complaint "must contain allegations that... [the directors] either participated in the day-to-day corporate activities or had a special relationship with the corporation, such as participation in preparing or communicating group information at particular times." GlenFed, 60 F.3d at 593. This Court ruled in BP Prudhoe that the group pleading doctrine survived enactment of the PSLRA. 2007 WL 3171435 *7. Defendants do not challenge that ruling here.

The allegations in the Complaint are insufficient to apply the group pleading doctrine to Defendants Dziurzynski and Kunath. Plaintiffs allege that both Defendants are directors of Dendreon, and that "[b]ecause of their positions of control and authority with the Company, the Individual Defendants (including Dziurzynski and Kunath) possessed the power and authority to control the contents of Dendreon's annual and quarterly reports, press releases.... [and had] access to material non-public information[.]" (Compl. ¶¶ 22-23.) But Plaintiffs fail to allege that either Dziurzynski or Kunath were involved in the "day-to-day" activities of Dendreon or that they had a special relationship with the company. See GlenFed, 60 F.3d at 593 (holding that it is insufficient to plead only identity and general responsibilities of outside directors without demonstrating participation in corporate activities). The allegedly misleading statements by Defendants cannot be attributed to both Defendants Dziurzynski and Kunath under the group pleading doctrine and therefore the claims against those Defendants shall be dismissed.

B. Press releases

Plaintiffs argue that certain press releases were misleading because they did not disclose the fact that the FDA had issued a Form 483. Plaintiffs focus on the following press releases:

1) The March 1 press release:

> [The FDA]... will review the Biologics License Application for PROVENGE, the Company's investigational active cellular immunothereapy for the treatment of asymptomatic, metastatic, androgen-independent prostate cancer on March 29, 2007.... Based on the FDA's designation of Priority Review for PROVENGE, the Company anticipates action by the FDA approximately six months from the submission date, or by May 15, 2007.

(Greene Decl., Ex. A-1.)

2) The "Recent Highlights" section of a March 14 press release (filed as an exhibit with Dendreon's Form 8-K):

> • Completed rolling submission of Biologics License Application to [the FDA].
> • FDA accepted BLA filing and assigned Priority Review status and a [Complete Response Date] for completion of review of the Provenge BLA by May 15, 2007.
> • PROVENGE will be reviewed by the FDA's [Advisory Committee] on March 29, 2007.
> • Preliminary results from ongoing PROTECT clinical trial indicated the drug's potential to benefit patients with earlier-stage prostate cancer.
> • Gregory T. Schiffman... joined Dendreon as Senior Vice President and Chief Financial Officer.

(Greene Decl., Ex. K-5.)

3) The March 29 press release:

> Dendreon Corporation today announced that the [FDA Advisory Committee] recommended to the FDA that there is substantial evidence of efficacy and safety of PROVENGE for the treatment of patients with [prostate cancer].... The FDA will now review the advisory committee's recommendations. The Company anticipates a decision on PROVENGE by May 15, 2007.

(Greene Decl., Ex. J-6.)

The Court concludes that none of the statements in the above-listed press releases were rendered misleading by the failure to disclose the Form 483. Dendreon did not assert or imply in the press releases that Provenge would be approved by the Complete Response Date or any other date certain. Plaintiffs argue that Defendants had knowledge that the manufacturing facility failed a mandatory CMC inspection, and that that failure created a "high probability" of delayed FDA approval. (Compl. ¶ 46.) Even assuming that the observations in the Form 483 were serious enough to make that allegation accurate, Plaintiffs fail to specifically identify any language in the press releases in which Dendreon predicted the successful licensing of Provenge by a particular date. Compare Warshaw v. Xoma Corp., 74 F.3d 955, 959-60 (9th Cir. 1996) (holding that plaintiffs met their pre-

PSLRA burden by pointing to multiple positive statements about efficacy and likely approval of drug that defendants made while knowing that studies indicated the drug might not work and would never be approved by the FDA). Here, Defendants stated in their press releases only that they expected FDA action by the anticipated Complete Response Date. (See Greene Decl., Ex. A-1.) Because none of the above statements suggested that approval was expected by the Complete Response Date, and because Plaintiffs point to no other reason why the statements were misleading, Plaintiffs fail to meet their burden of showing the misleading nature of the statements. See In re Silicon Graphics, 183 F.3d at 985.

Plaintiffs point to Yanek, in which the Central District of California held that despite failing to "individually specify each statement alleged to have been misleading," plaintiffs met their burden. 388 F. Supp. 2d at 1121. Not only is this Court not bound by Yanek, Yanek is distinguishable because the problems identified with that defendant's manufacturing facility were severe, making the statements regarding likely FDA approval more misleading. In this case, Plaintiffs have failed to plead with particularity how any statements in the press releases were false or misleading.

C. 2006 Form 10-K

Plaintiffs also argue that Dendreon's 2006 Form 10-K falsely implied that no inspection had occurred in that it listed "every other fact relevant to the BLA" other than the February inspection and issuance of the Form 483. (Compl. ¶ 49.) Specifically, Plaintiffs point to one section of the Form 10-K which stated:

> On August 24, 2006, we (Dendreon) submitted the clinical and non-clinical sections of our BLA and on November 9, 2006, we submitted the chemistry, manufacturing and controls section, completing our submission of our BLA to the FDA for Provenge. On January 12, 2007 the FDA accepted our BLA filing and assigned Priority Review status for Provenge. The [Complete Response Date] for the anticipated completion of review by the FDA of our BLA is May 15, 2007. Provenge will be reviewed by the FDA's [Advisory Committee] on March 29, 2007.

(Compl. ¶ 49.) As with the press releases, Plaintiffs have failed to identify which

statement in the above excerpt was rendered misleading by omitting mention of the Form 483. See Brody, 280 F.3d at 1006 (holding that Rule 10b-5 does not prohibit statements that are only incomplete).

Plaintiffs also argue that Defendants' "falsely and misleadingly implied that the CMC inspection had not yet occurred." (Compl. ¶ 50.) Plaintiffs cite an excerpt from the "Ongoing Regulatory Requirements" section of the 2006 Form 10-K, which stated:

> Before approving a [BLA], the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with [FDA regulations].

(Compl. ¶ 50; Greene Decl., Ex. L-5.) The 2006 Form 10-K also stated:

> Our facilities and quality systems... must pass a pre-approval inspection for compliance with the applicable regulations as a condition of FDA approval of Provenge or any of our other potential products[.]

(Compl. ¶ 50.) Lastly, Plaintiffs allege that statements in the "Risk Factors"section were misleading because they implied no inspection had occurred and no Form 483 had been issued. Plaintiffs point to Dendreon's statement that "the FDA may determine that our manufacturing... facilities... are insufficient to warrant licensure." (Greene Decl., Ex. L-6.)

The Court concludes that Plaintiffs have not sufficiently alleged that the statements in the 2006 Form 10-K were misleading. First, the section of the 2006 Form 10-K that allegedly implied no inspection had occurred is a general description of the BLA approval process, which applies to all of Dendreon's products, not just to Provenge. See Anderson, 140 F. Supp. 2d at 905 (holding that failure to update "boiler plate" regulation section not misleading because "no reasonable investor would infer anything about the state of [defendant's] FDA compliance"). Second, Plaintiffs inappropriately conflate the CMC inspection and issuance of a Form 483 with a finding of non-compliance. A statement that the product will not be approved unless the manufacturing facilities are in compliance is not misleading for failing to mention a Form 483 because the Form 483 is not a final agency determination of non-compliance. (See Greene Decl., Ex. I-8.)

Plaintiffs argue that the press releases and SEC filings were misleading, as a whole,

because they gave "an impression that the Company was steadily marching towards likely approval, while the reality was that approval by the [Complete Response Date] was highly unlikely given the issues cited by the FDA inspectors in the Form 483." (Plfs.' Opp'n at 12-13.) But the law requires a plaintiff to identify and specify the reasons why a particular statement is misleading. See In re Vantive Corp. Sec. Litig., 283 F.3d 1079, 1089-90 (9th Cir. 2002); see also 15 U.S.C. § 78u-4(b)(1). Plaintiffs cannot abrogate their burden to plead with particularity why specific statements were misleading.

D. Conference Call

During a conference call on March 29, 2007, Defendant Gold had the following interchange with securities analyst Charles Duncan:

> **Duncan**: Okay. Then final question with regard to time lines do you anticipate having to submit any additional information with regard to kind of the validation of you manufacturing processes?
>
> **Gold**: Sure. One of the things that we did as part of our [BLA] with the FDA, in particular the CMC section was to submit a lot of manufacturing data. As part of that, the FDA came out we hosted them for preapproval inspections at our Hanover, New Jersey, facility.
>
> **Duncan**: Okay. Those facilities obviously passed the muster, or can you give us any more insight?
>
> **Gold**: Actually, those are activities that we'll be discussing with the agency between now and the [Complete Response Date] so its actually, we hosted a good inspection, I think, and we have ongoing discussions with them between now and between May 15, to finish the review of the CMC section.

(Greene Decl., Ex. D-2.) Plaintiffs did not include this conference call in their Complaint because the transcript was unavailable at the time the Complaint was filed. Plaintiffs seek leave to amend the Complaint to include information about this conference call. In light of the potential significance of the above statements, the Court grants Plaintiffs leave to amend the Complaint because it is not reasonably certain that the amendment "would be futile at this point." See In re Loudeye Corp. Sec. Litig., 2007 WL 2404626 *11 (W.D. Wash. 2007).

III. Scienter

Scienter in the § 10(b) context is a "mental state embracing intent to deceive, manipulate, or defraud." Silicon Graphics, 183 F.3d at 975 (citations and internal quotation marks omitted). The PSLRA "requires that the [c]omplaint state with particularity facts giving rise to a strong inference that the defendant acted with [scienter]." Nursing Home Pension, Local 144 v. Oracle Corp., 380 F.3d 1226, 1230 (9th Cir. 2004) (citations and internal quotation marks omitted). In order for the inference of fraudulent intent to be strong, it must be "more than merely plausible or reasonable-it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, 127 S. Ct. at 2504-05, 2510. Inferences negative to the plaintiff must also be considered. Gomper v. VISX, 298 F.3d 893, 896-98 (9th Cir. 2002). The Court is to look at all the facts alleged collectively, "not whether any individual allegation, scrutinized in isolation, meets that standard." Tellabs, 127 S.Ct. at 2509.

Plaintiffs must show that each Individual Defendant had the requisite scienter. For scienter to be attributed to Dendreon, Plaintiff must sufficiently plead that at least one of the Individual Defendants had the requisite scienter while making the allegedly misleading statements. See In re Apple Computer, Inc. Sec. Litig., 243 F. Supp. 2d 1012, 1023 (N.D. Cal. 2002). Plaintiffs allege that the Individual Defendants knew or recklessly disregarded the risk that Dendreon's investors would be misled by failing to disclose the issuance of the Form 483. Plaintiffs argue that fraudulent intent can be further inferred from Defendants' stock sales.

The Court concludes that Plaintiffs have not sufficiently plead scienter. First, the Court cannot draw any inferences from the alleged severity (or lack thereof) of the issues identified in the Form 483. Compare Yanek, 388 F. Supp. 2d at 1125-30 (drawing inferences of scienter from serious and multiple issues identified in Form 483). Second, Defendants' stock sales do not provide circumstantial evidence of the requisite scienter. To create any inference of scienter, let alone a strong one, Plaintiffs must allege that the stock sales are not only unusual or suspicious, but also "dramatically out of line with prior

trading practices." Silicon Graphics, 183 F.3d at 986 (citations and internal quotation marks omitted). Courts look at three factors when deciding if a plaintiff meets this burden: (1) the amount and percentage of shares sold by the insider; (2) the timing of the sales; and (3) whether the sales were consistent with the insider's prior trading history. Id. Plaintiffs fail to plead facts showing that any Defendants' stock sales were "dramatically out of line with prior trading practices." On April 2, 2007, Defendant Gold sold 24.5% of his Dendreon shares. (Compl. ¶ 62; see Greene Decl., Ex. M.) Even much higher percentages have been held to not provide a strong inference of scienter, particularly when a plaintiff fails to provide the prior trading history of the defendant. See Ronconi, 253 F.3d at 435-36 (complaint dismissed even though defendants sold between 69% and 98% of shares, because plaintiff failed to show the trading was dramatically out of line with prior trading history).[2]

Moreover, the timing of the stock transactions is not suspicious or unusual. All of the stock sales took place within the first ten days of the Advisory Committee's positive vote for the licensing of Provenge on March 29, 2007. (See Compl. ¶¶ 62-65.) The negative inferences from the timing of these transactions are not "at least as compelling" as the positive. See Tellabs, 127 S.Ct. at 2510; see also Lipton, 284 F.3d at 1037 ("Officers of publicly traded companies commonly make stock transactions following the public release of quarterly earnings and related financial disclosures.") The Advisory Committee's recommendation has a substantial impact on the likelihood of approval from the FDA and it is not suspicious that directors and officers would trade during this period. (See Compl. ¶ 60 ("[t]he FDA rarely rejects a BLA after [the Advisory Committee] recommends approval")). Additionally, the fact that three other Individual Defendants did not sell their shares undermines Plaintiffs' scienter argument. See Ronconi, 253 F.3d at

[2] The stock sales of Defendants Dziurzynski and Kunath are immaterial because the claims against those Defendants are dismissed. See supra Discussion, section II(A).

436 ("One insider's well timed sales do not support the 'strong inference' required by the statute where the rest of the equally knowledgeable insiders act in a way inconsistent with [the fraudulent inference].") Because Plaintiffs have failed to sufficiently plead scienter, their Rule 10-5 claim fails. See 15 U.S.C. § 78u-4(b)(3)(A).

IV. Loss Causation

The parties dispute whether Plaintiffs have adequately plead loss causation. Under Rule 10b-5, a plaintiff shows loss causation by illustrating a "causal connection between the material misrepresentation and the loss." Dura, 544 U.S. at 342. Although it is insufficient for a plaintiff to allege only that at the time he purchased his stock, the price was inflated by the defendant's misrepresentations, a heightened pleading standard does not apply to loss causation. Immune Response, 375 F. Supp. 2d at 1024-25.

Plaintiffs argue that the stock price of Dendreon would "never have risen as high as it did had the investing public known that the FDA had raised CMC concerns and... had issued a Form 483" and that when Defendants' "concealed information" was made public, Plaintiffs were caused harm by the drop in stock price. (Compl. ¶ 75.) Plaintiffs point to the drop in stock price on May 9, the first day that the market reacted to the FDA's request for additional information. Plaintiffs also cite a statement from Defendant Urdal at the May 10 conference call, where he admitted the Form 483 had been issued and "that the Complete Response cited those same violations." (Compl. ¶ 69.) Thus, Plaintiffs' Complaint includes allegations linking the alleged misrepresentations to the drop in Dendreon's stock price.

Defendants argue that Plaintiffs' loss was caused by the FDA's efficacy concerns, not the CMC concerns. They point out that although Dendreon's stock price dropped after the FDA's negative decision was made public on May 9, the price actually increased after Dendreon discussed the issuance of the Form 483 at the May 10 conference call. But the alleged facts indicate that the CMC issues in the Form 483 were at least part the reason why the FDA refused to approve Provenge. See In re Daou Systems, Inc., 411

F.3d 1006, 1025 (9th Cir. 2005) (a plaintiff is not required to show that "a misrepresentation was the sole reason for the investment's decline in value," but only a substantial cause) (citation and internal quotation marks omitted). Moreover, Defendants incorrectly focus on the date they discussed the Form 483 itself, rather than the previous date when the CMC issues identified in the Form 483 were revealed. On May 9, the FDA's previously undisclosed CMC concerns-the ones identified in the Form 483-were made public. Plaintiffs have sufficiently plead that the disclosure of this previously concealed information caused the stock price to decline.

V. Section 20(a)

To support a claim under § 20(a), a plaintiff must first state a claim under § 10(b) or Rule 10b-5. See Lipton, 284 F.3d at 1035 n.15. Because Plaintiffs have failed to plead with particularity or state a claim under Rule 10b-5, their § 20 claim fails.

Conclusion

Plaintiffs have failed to plead with particularity all facts showing that Defendants' statements were misleading and made with the requisite scienter. Defendants' Motion to Dismiss is therefore GRANTED. Plaintiffs are GRANTED leave to amend their Complaint. Any such amendment shall be filed within thirty (30) days of this order.

The Clerk is directed to send a copy of this order to all counsel of record.

Dated: April 18, 2008.

s/Marsha J. Pechman

Marsha J. Pechman

United States District Judge